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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/100,633 06/19/98 HUTCHENS

T 016866-00220

EXAMINER

HM22/0212

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ART UNIT PAPER NUMBER

1627
DATE MAILED:

02/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/100,633

Applicant

Hutch ns t al

Examiner
T. Wessendorf

Group Art Unit
1627



☒ Responsive to communication(s) filed on 11/30/00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 76-90 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 76-90 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76-90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record, reiterated under paragraph A, below.

A). The specification does not provide an adequate written description of the various components in order to reasonably practice the claimed method. The specification merely provides an unspecified description of the claimed components. For example, page 24, lines 1-6 defines the agent as a chemical compound, a mixture of chemical compounds, a sample of undetermined composition and etc. An agent of undetermined composition encompasses myriads of agents to which the specifically exemplified single agent of known composition would not provide as sufficient description of the infinite numbers of agents.

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Furthermore, the claims cover too numerous undefined or incompletely described parameters, besides the agent, such as a substrate, substrate-bound ligand or receptor, small organic molecule, linker, a cell surface receptor, intracellular receptor, cell membrane, linker, detectable moiety, combinatorial library and importantly, the conditions for the specific interactions of the different unspecified components to occur. Given the single embodied species which describes only a part of the invention, the specification, specifically, Example X1, which should supposedly directs or aids a skilled artisan in the practice of the claim, would be insufficient to describe the various infinite variables covered by the claimed invention. It is not apparent from the specification how can one be led to a particular combination of the various parameters e.g., the agent, substrate, reaction conditions for the successful practice of the claimed invention. Also, the specification fails to describe the method by which the substrate is bound to a linker e.g., the means or positions by which these linkers bind either to the receptor or ligands.

It is argued that the cancellation of the claims and presentation of the new claims, this rejection has been obviated.

~~However, even the newly presented claims, contain all the~~
numerous undefined variables, as the canceled claims. For

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example, the agent being a small organic compound is not adequately described in the specification i.e., as to what constitute a small organic compound. Note that the specification, page 69 recites small molecule and not small organic molecule.

[Note that the claims appear to omit the essential features of the invention i.e., the use of a retentate chromatography as exemplified by the given Examples and detection by spectrometry.]

B). Newly presented claim 78 drawn to a probe that is removably insertable in the mass spectrometry is not supported in the as-filed specification. Applicants point out support in page 27, lines 16-17. Page 27 of the original disclosure recites "...a probe inserted into a desorption detector." That is, a probe that is positively inserted into the detector and not one that may or may not be inserted. Also, claims 85-88 are not supported in the as-filed specification. Cf. with Example XI at page 99 of the instant disclosure. Page 27, line 28 is relied to support claim 85. However, the cited page relates to the derivation of the surface rather than a linker that links either one of the pair to the substrate. Also, the disclosure does not recite for Fc fragment as a detectable moiety. Thus, these claims present different concepts than what are disclosed.

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The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 76-90 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 76 is indefinite in that the method steps do not contain a step by which screening occurs. The preamble recites for a method for screening but the body of the claims recite for steps for determining whether the agent modulates the reaction between a target analyte and an adsorbent.

It is argued that with the cancellation of the previous claim 30, the rejection of the claim is obviated. However, this rejection has not been obviated even with the cancellation of the previous claims as this limitation still appears in the present claim. Thus, while the preamble

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recites screening and would require screening from e.g., a library or collection of agents however, the body of the claims does not recite for any screening step or assay. Rather, the body of the claims recite comparing the modulating effect of the agent from that of a control to determine the modulating effect of the agent. Also, the recitation of "corresponding", within the claimed context is unclear, i.e., in what aspects the pair correspond with one another. [Binding appears more appropriate.] Step © is unclear as to whether the desorbing and ionizing is with respect only to either one of the pair being desorbed and ionized or both the bound pair being ionized and desorbed from the substrates. Cf. with Example XI at page 99 of the instant disclosure which describes measurement of the components bound to the adsorbent or substrate i.e., retentate chromatography wherein all the components being analyzed are retained in the substrate.

Step (d) recitation of a "control amount" is ~~unclear and the term lacks antecedent support from~~ the instant specification. [Reciting a step of

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determining whether the agent modulates binding by comparing the measured amount of binding in the presence and absence of the agent is consistent with the disclosure.] Furthermore, it is suggested that "modulates" be changed to --inhibits--.

B). Claim 78 "the mass spectrometer" lacks antecedent basis of support from the base claim.

C). Claim 86 is confusing. Is the antibody a linker as what appears to be claimed or is it either a receptor or a ligand bound to the substrate?

D). Claim 87 is unclear as to how either the receptor or ligand bound substrate is comprised within a fusion protein. Is the receptor, for example, embedded in a fusion protein? Cf. with Example XI.

E). Claim 90 broadens the base claim which does not recite for a combinatorial library of the agents rather, only an agent that modulates reaction between a ligand/receptor. Cf. (again) with Example XI.

F). Claim 89, for example, is indefinite in that it fails to point out what is included or

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excluded by the claim language. This claim is an omnibus type claim. Note the specification recites "small molecule" and not small organic molecule, as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 76-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel in view of Kauvar (WO 89/09088) for reasons of record.

J. of Mass Spectrometry
vol 33
264-273
(1998)

It is argued that since the abstract present only a preliminary reports of the publication hence, it is unclear whether the abstract is a fair representation of the whole article. It is not clear why the abstract, which is a synopsis of ~~the whole article, is not considered as a fair~~ representation of Siegel's entire disclosure. The

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later published work of Siegel with the same abstract, clearly provides evidence supporting the abstract.

Applicants implicitly admit that the abstract in the 1998 publication were a fair representation of the disclosure at the meeting. But argue that Siegel does not disclose desorption mass spectrometry rather electrospray spectrometry. However, it would be within the ordinary skill in the art to pick and choose the kind of mass spectrometry measurement available in the art i.e., electrospray or desorption/ionization technique.

Applicants acknowledge that Kauvar describes methods for designing and producing paralogues that have a specific affinity for a desired analyte so that the paralogues can be used as a substrate to bind the desired analyte. And suggest using paralogues as a substitute for antibodies that bind the desired analyte. But argue that Kauvar does not use paralogues to inhibit binding of antibody to antigen. As applicants stated, Kauvar teaches these paralogues as substitute for antibodies.

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Hence, in order to determine that these paralogues are substitute Kauvar would (implicitly), if not expressly, teaches that such paralogues would have a modulating effect (even if not inhibiting) against the reaction of an antibody (not the paralog) and antigen.

It is further argued that Siegel teaches away from the claimed invention by citing the present inventors' work. However, the mere fact that Siegel discloses that the affinity chromatographic techniques may not be very rapid or sensitive does not indicate a teaching away from the claimed invention. Rather, merely presents the methods known in the art.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

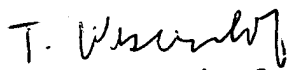
Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be

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retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


T. Wessendorf
Patent Examiner
Art Unit 1627
2/9/01